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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,784	05/26/2000	Christopher L. Baszczyński	5718-23B	9894

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ALSTON & BIRD LLP
PIONEER HI-BRED INTERNATIONAL, INC.
BANK OF AMERICA PLAZA
101 SOUTH TYRON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.
09/579,784

Applicant(s)
Baszczynski et al

Examiner
Jane Zara

Art Unit
1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 13, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-24, and 27-29 is/are rejected.
- 7) ☒ Claim(s) 11, 12, 25, and 26 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12, 14 6) ☐ Other:

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DETAILED ACTION

This Office action is in response to the communication filed 9-13-02, Paper No. 11.

Claims 1-29 are pending in the instant application.

The sequence amendment filed 1-13-03, Paper No. 16, has been received and entered.

Any rejections not repeated in this Office action are hereby withdrawn.

Response to Arguments and Amendments

Maintained Rejections

Claims 1-8, 13-22, 27-29 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement over the scope claimed for the reasons of record set forth in the Office action mailed 4-9-02, Paper No. 9.

Applicant's arguments filed 9-13-02 have been fully considered but they are not persuasive. Applicants argue that a reasonable amount of guidance has been provided in the instant disclosure whereby the claimed invention is fully enabled. Contrary to Applicants' assertions, the teachings provided in the instant disclosure, comprising the ability to introduce nucleotide conversions into the previously characterized AHAS target gene, and the ability to introduce nucleotide conversions within an episomal plasmid comprising the previously characterized target gene PAT/GFP, are not representative of the ability to predictably introduce nucleotide conversions into the genome of any plant comprising any previously transfected target gene. In the experiments regarding introducing nucleotide conversions into the previously

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characterized target AHAS gene, for instance, unexpected sequence changes were obtained using the chimeric nucleotides claimed (e.g. page 29 of the specification). Furthermore, the ability to predictably introduce nucleotide conversions into a target gene within an episomal plasmid is not representative of the ability to introduce such conversions into any target gene previously integrated within the genome of any plant.

Applicants argue that considerable amount of routine experimentation is permissible if reasonable amount of guidance is provided by the specification. Contrary to Applicants' assertions, inactivating any target gene introduced into the genome of any plant cell by introducing a chimeric oligonucleotide comprising two RNA blocks flanked by a DNA residue block, whereby the RNA blocks are homologous to the target nucleotide sequence, requires more than routine experimentation. The success of target gene inactivation using the chimeric constructs claimed is dependent upon many factors, including the higher order structure of the host genome at the place of target gene insertion, target gene structure and the repair mechanism(s) of the host plant exploited for target gene inactivation using the highly variable chimeric constructs claimed. The examples provided in the instant disclosure are not representative of the ability to inactivate any and/or all target genes inserted into the genome of any plant host using the chimeric structures claimed.

Applicants argue further that no undue experimentation is required to enable the full scope of the claimed invention. Contrary to Applicants' assertions, it would require undue experimentation to practice the invention drawn to introducing nucleotide conversions into any

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previously integrated target gene within any plant genome comprising introducing into the plant a chimeric oligonucleotide having a first block of RNA and a second block of RNA, which RNA residues are homologous to the target nucleic acid molecule, and which RNA residues flank a block of DNA residues. The length of the RNA blocks, DNA residues, higher order structure of the plant genome and the target gene, as well as the place of target gene integration within the plant genome, all contribute to the uncertainty of the success of the method claimed. It would require undue experimentation beyond the examples provided in the instant disclosure to address these variables. Therefore the rejection for lacking enablement over the broad scope claimed is maintained.

New Rejections

Double Patenting

Claims 1-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-24 of copending Application No. 09/580,747. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are drawn to a method of introducing nucleotide interconversions into a target gene within the genome of a plant comprising introducing a chimeric oligonucleotide into the plant, which chimeric oligonucleotide comprises a first block of RNA and a second block of RNA, which RNA residues are homologous to the target nucleic acid molecule, and which RNA residues flank a block of DNA residues.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 13-24, 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear in claims 1 and 16, lines 7- 8, how the blocks of the RNA residues can be homologous to the nucleic acid molecule. Appropriate clarification is requested.

In claim 16, line 6, "oligonulceotide" should perhaps be replaced with --oligonucleotide--.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 13-24, 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising chimeric oligonucleotides comprising a first and second block of RNA residues that are homologous to a nucleic acid molecule comprising a promoter operably linked to a nucleotide sequence comprising a gene. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number structural differences between members of this broad genus is permitted (e.g. What are the lengths of each of the RNA blocks, or the length of nucleotides in the DNA portion of the chimeric constructs claimed?). Concise structural features that could distinguish compounds in the genus from others is missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

The specification does not describe the elements that are essential to various functions of the claimed invention, which elements include those which are essential to the definition of “gene”, which include naturally occurring regulatory elements, untranslated regions, and/or those elements which mediate the expression of a particular gene in a particular cell type, and which elements are empirically determined and not disclosed.

Since the disclosure fails to describe the characteristics (e.g. nucleotide sequences) concisely identifying members of the proposed genus comprising chimeric oligonucleotides of a first and second block of RNA residues homologous to any and/or all promoters operably to any and/or all genes, including any and/or all herbicide resistant gene, and flanking any DNA residues,

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and because the genus claimed is highly variant, the description provided defining members of the genus is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide adequate description for the broad genus claimed. Thus, Applicant was not in possession of the claimed genus.

Allowable Subject Matter

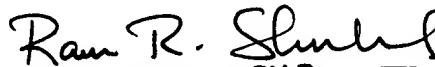
Claims 11, 12, 25, 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


RAM R. SHUKLA, PH.D.
PATENT EXAMINER

JZ

March 24, 2003